

REMARKS

Claims 39-58 are pending. Claims 39-44 are withdrawn from consideration as being drawn to a nonelected invention. Claim 51 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 45, 47, 52-53, and 55-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sugano et al., U.S. Patent No. 4,416,606 ("Sugano"). Claim 58 stands rejected under 35 U.S.C. § 102(b) as being anticipated by either Sugano or by Gamlen et al., *Drug Development and Industrial Pharmacy* 12:1701-1715, 1986 ("Gamlen"), or, in the alternative, under 35 U.S.C. § 103(a) as obvious over either Sugano or Gamlen. Claims 48 and 54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sugano. Claims 45-46, 48-54, and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gamlen in view of Sugano.

Claim Amendments

Claims 40-44 and 46-57 have been amended to correct formal matters. Claim 58 has been cancelled.

New claims 59-66 have been added. Claim 59 finds support in the specification, for example, at page 13, lines 25-30. Claim 60 finds support in the specification at, for example, page 9, line 33-page 10, line 3. Claims 61-64 find support in the specification, for example, at page 10, lines 13-16 and at page 17, line 31-page 18, line 2. New claim

65 finds support in the abstract of the application as filed as well as in the abstract of U.S. provisional patent application 60/429214 as filed. No new matter has been added.

These amendments have been made to advance prosecution. Applicants reserve the right to pursue any cancelled subject matter in this or a continuing application.

Rejection under 35 U.S.C. § 112, Second Paragraph

The Office has rejected claim 51 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. The Office asserts that the phrase “a poorly soluble drug belonging to Class II or Class IV of the Biopharmaceutical Classification System [BCS]” is indefinite because the term “poorly” is a relative term and the Biopharmaceutical Classification System is subject to change. Applicants respectfully traverse this rejection.

Claim 51, as amended, reads as follows:

The continuous wet granulation process according to claim 45, wherein said powder material contains a poorly soluble drug belonging to Class II or Class IV of the Biopharmaceutical Classification System.

The classes of the Biopharmaceutical Classification System (“BCS”) relate to the solubility ranges found in Amidon et al., *Pharm. Res.*, 12:413-420 (1995) (“Amidon”). Amidon is discussed in the specification (for example, page 21, line 32-page 22, line 4). Amidon was cited in the Information Disclosure Statement filed September 23, 2005, and

has been considered by the Office. The BCS is a widely accepted classification system, and use of the BCS is conventional in drug technology. For example, the U.S. Food and Drug Administration provides information and guidance regarding the BCS (see, for example, http://www.fda.gov/cder/OPS/BCS_guidance.htm). As such, the BCS, and therefore the drug classes encompassed by the BCS (e.g., class II and class IV drugs as recited in claim 51), are terms whose meaning is known to those practicing the art. Class II and class IV drugs, as recited in claim 51, are described respectively as “high permeability, low solubility” and “low permeability, low solubility” drugs in the BCS. Because class II and class IV compounds are, by definition, poorly soluble, the use of the term “poorly soluble” in claim 51 is consistent with the BCS standards, and therefore the claim should not be considered indefinite. Given that the BCS is an established classification system and that, moreover, physical properties such as solubility are absolute properties, Applicants disagree that the BCS is subject to change. This ground for rejection should therefore be withdrawn.

Rejection under 35 U.S.C. § 102(b) - Claims 45, 47, 52-53, and 55-56

Claims 45, 47, 52-53, and 55-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sugano.

In rejecting claims under 35 U.S.C. § 102, “[a] single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim

by anticipation.” *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005) (citing *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992)). See also *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994). “Anticipation of a patent claim requires a finding that the claim at issue ‘reads on’ a prior art reference.” *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) (quoting *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985)).

Sugano fails to meet this test.

The Office asserts that Sugano teaches a continuous wet granulation method that includes the steps of:

feeding a powder...to a first transport zone (fig 1 zone 1), feeding a liquid... into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (fig 1 zone II₁), transporting the mixture to a second transport zone further downstream (fig 1 zone II₂) and discharging the resulting granules without submitting them to any pressure gradient (fig 5 part 8).

Sugano’s Figure 1 and Figure 5 are reproduced below:

Fig. 1

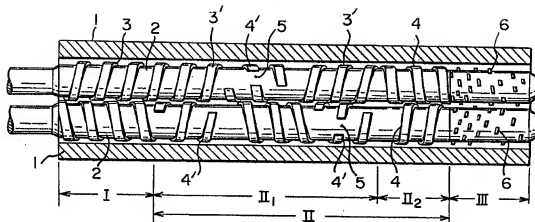
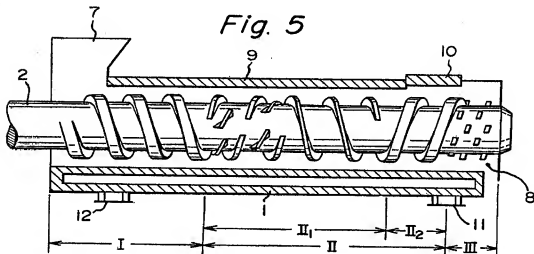


Fig. 5



Applicants disagree with the Office's interpretation of Sugano. Step (e) of claim 45 requires the direct discharge of granules from the second transport zone without submitting the granules to any pressure gradient. First, according to the Examiner, Sugano teaches "transporting the mixture to a second transport zone further downstream (fig 1 zone II₂) and discharging the resulting granules without submitting them to any

pressure gradient (fig 5 part 8).” Sugano teaches that material from the kneading zone is sent to the breaking zone III. Accordingly, because there is no direct discharging of granules from “zone II₂,” Sugano fails to satisfy this limitation. Moreover, the Examiner does not direct applicant to where Sugano teaches directly discharging granules without submission to any pressure gradient. Sugano’s method fails to meet the requirements of applicants’ claim 45, where granules are directly discharged from the second transport zone “without submitting [the] granules to any pressure gradient.” Accordingly, Sugano fails to anticipate claim 45 and this rejection should be withdrawn.

Rejection under 35 U.S.C. § 103(a) - Claims 46 and 54

The Office has rejected claim 46 and 54 as being obvious under 35 U.S.C. § 103(a) over Sugano as applied to claim 45.

Each of claims 46 and 54 depends from claim 45, and incorporates the limitations of claim 45. “[O]bviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Even assuming for arguments’ sake that the additional agglomeration zones (claim 46) and operating temperature (claim 56) would have been obvious to an ordinary artisan, the Examiner has not explained why the artisan would have been prompted to modify Sugano’s teachings to arrive at a method that includes a step of “directly discharging ... granules from [the] second transport zone ... without

submitting [the] granules to any pressure gradient” as recited in claim 45. Thus, because the Examiner has not adequately explained why Sugano meets all of the limitations in claims 46 and 54, each of these rejections should also be withdrawn.

Rejection under 35 U.S.C. § 103(a) - Claims 45-46, 48-54 and 57

The Office has rejected claims 45-46, 48-54, and 57 as being obvious under 35 U.S.C. § 103(a) over Gamlen in view of Sugano.

The Office finds that Gamlen teaches mixing powder and liquid and granulating the mixture to make pharmaceutical pills. The Office further finds that Gamlen’s method “involves the continuous ... extrusion of the mixture through a perforated plate.” Furthermore, the Office, relying on column 1, lines 33-39, finds that Sugano teaches “that extruding the mixture through a perforated plate requires one to constantly replace the clogged plate.” To remedy the deficiency in Gamlen, the Office concludes that “it would have been obvious to replace the extrusion steps taught by Gamlen with the steps taught by Sugano because Sugano’s steps eliminate the problem of stopped-up extrusion plate.”

As applied by the Examiner, the Sugano reference does not remedy the deficiencies of Gamlen. Sugano, as is discussed above, does not describe step (e) of claim 45 that requires “directly discharging ... granules from [the] second transport zone ... without submitting [the] granules to any pressure gradient.” Further, the Examiner

does not provide any explanation as to why one of ordinary skill in the art would have been led by Sugano to the step of directly discharging granules or directly discharging the granules without a pressure gradient besides asserting that Sugano describes the limitation. Sugano simply would not lead one of ordinary skill in the art to a method of claim 45.

Because the Office has failed to present a *prima facie* case of obviousness, the rejection of claim 45 should be withdrawn. Claims 46, 48-54, and 57 depend from claim 45. The rejections of these claims should likewise be withdrawn.

Claim 47

For the reasons discussed above, claim 47 is free of the cited prior art and is therefore allowable.

Claim 60

Claim 60 is directed to a continuous wet granulation process that “avoids the use of a die, die block, die plate, die screen or any other similar device having the function or result of forcing the granulate to produce an extrudate of a required section by creating a specific pressure gradient in the terminal portion of said continuously operated transporting means.” Neither Sugano nor Gamlen, alone or in combination, teach or suggest such a method. Claim 60 is likewise allowable.

Claim 65

Claim 65 is directed to a continuous wet granulation process that transports agglomerated material from the agglomeration zone (5) to a second transport zone (8) where the second transport zone has an aperture (9) positioned collinearly to the continuously operating transport system and directly discharges granules from the second transport zone (8) through the aperture (9). Sugano, like Gamlen, fails to teach such a method.

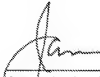
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 5/15/2009



James D. DeCamp
Reg. No. 43,580

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045